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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,946	05/02/2001	Michael J. May	PPI-119	6173
959 7590 01/15/2004 LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			EXAMINER DESAI, ANAND U	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,946

Applicant(s)

MAY ET AL.

Examiner

Anand U Desai

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13 is/are rejected.
- 7) ☒ Claim(s) 6 and 11-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the peptide comprising SEQ ID NO: 131 filed December 1, 2003 is acknowledged. The traversal is on the ground(s) that the peptides encompassed by the claims clearly represent a single invention in that they are connected in design, operation, and effect, i.e., are not independent inventions.

The requirement is still deemed proper and is therefore made FINAL.

Priority

It is noted that Applicants have claimed priority to SN 60/201,261 (May & Ghosh) filed May 2, 2000 and to SN 09/643,260 (May & Ghosh), filed August 22, 2000. Neither application teaches elected SEQ ID NO: 131. At page 46 of SN 60/201,261 and at page 47 of SN 09/643,260 the following sequence is set forth:

DRQIK IFWQN RRMKW KKTAL DWSWL QTE

In no place in either application does the specification teach the fragment RRMKW KKTAL DWSWL QTE, which corresponds to instant SEQ ID NO: 131. Thus, priority is denied to either priority application. **The priority of the instant application is set to its filing date, May 2, 2001 for SEQ ID NO: 131.**

Specification

1. The disclosure is objected to because of the following informalities:

There is a typographical error: Page 5, line 13 the word "compound s" should be "compounds".

The specification contains underlined words, such as amino acid symbols, W for Tryptophan on page 48, which is normally intended to indicated added matter. See 37 CFR 1.121(b). Suggest removing underline.

(b) *Specification other than the claims and listings provided for elsewhere (§ 1.96 and 1.825). —*

(1) *Amendment by instruction to delete, replace, or add a paragraph.*

Amendments to the specification, other than the claims and listings provided for elsewhere (§§ 1.96 and 1.825), may be made by submitting:

- (i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a deleted paragraph with one or more replacement paragraphs, or add one or more paragraphs;
- (ii) Any replacement or added paragraph(s) in clean form, that is, without markings to indicate the changes that have been made; and
- (iii) Another version of any replacement paragraph(s), on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of the paragraph(s). The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added paragraph or a deleted paragraph as it is sufficient to state that a particular paragraph has been added, or deleted.

The use of the trademark "PCDNA-3" has been noted throughout this application, as well as "EXPAND LONG TEMPLATE PCR SYSTEM", on page 7, "FACSort", on page 8, "FUGENE 6", on page 9, and "STRATAGENE HYBRIZAP", on page 22. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

2. Claims 6, 11, 12 and 13 are objected to because of the following informalities:

The sequences disclosed are not in compliance with 37 CFR 1.821-1.825. Specifically see 37 CFR 1.821 2(d):

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO." in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

See also 37 CFR 1.822 (d) 1. The amino acids in a protein or peptide sequence shall be listed using the three-letter abbreviation with the first letter as an upper case character, as in WIPO Standard ST.25 (1998), Appendix 2, Table 3.

3. Claim 6, 12, and 13 are objected to because of the use of "," in the Markush group. Commas "," would be preferred.

Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of copending Application No. 09/643,260. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 19-21 in U.S. Patent Application 09/643,260 are directed to SEQ ID NO:2 which comprises Leu-Asp-Trp-Ser-Trp-Leu (current application, claim 6).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 3-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-25 and 35 of copending Application No. 09/847,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 16-25 and 35 in U.S. Patent Application 09/847,940 are directed to SEQ ID NO:18, which comprises Arg-Arg-Met-Lys-Trp-Lys-Lys-Thr-Ala-Leu-Asp-Trp-Ser-Trp-Leu-Gln-Thr-Glu (current application, claims 3-13).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 3-5, 7-11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A sequence identifier (SEQ ID NO.) is required for any amino acid sequence greater than 4 amino acids in length. In claims 3, and 7-10, the variable X_n, which is a membrane translocation domain is undefined? In claims 4 and 5, it is not clear where the additional amino acids are part of the claimed compound? Claim 11 is rejected for depending on rejected Claim 3. In claim 13, what "structure" is being claimed?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Art Unit: 1653

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 3-10, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by May et al. (May, Ghosh, Findeis, & Phillips; WO 01/83554; filed May 2, 2001; having priority to US SN 60/201,261 filed May 2, 2000, designating the US, in English).

May et al. teach RRMKW KKTAL DWSWL QTE as their SEQ ID NO: 131 at page 19, which corresponds to instant SEQ ID NO: 131. At page 48, DRQIK IFWQN RRMKW KKTAL DWSWL QTE is taught. Thus, May et al. teach peptides comprising SEQ ID NO: 131.

Claims 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothe et al. (January 14, 1999; WO 99/01541). Rothe et al. teach SEQ ID NO: 2 comprising: TALDWSWLQTE at amino acid residues 735-745. Therefore, Rothe et al. teach compounds comprising TALDWSWLQTE, LDWSWLQTE, TALDWSWL, ALDWSWLQTE, LDWSWLQTE, LDWSWL, TALDWSWLQT, TALDWSWLQ, ALDWSWLQT, LDWSWLQ, and LDWSWLQT. In SEQ ID NO: 4, LDWSWL is taught at amino acid residues 738-743, and peptides comprising the sequence are taught on page 4, line 9 as residues 737-745. Therefore, Rothe et al teach compounds comprising LDWSWL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (May, Ghosh, Findeis, & Phillips; WO 01/83554; filed May 2, 2001; having priority to US SN 60/201,261 filed May 2, 2000, designating the US, in English), in view of Applicants admissions in the election response filed December 1, 2003. The teachings of May et al. are set forth above. Applicants state that that the peptides encompassed by the claims clearly represent a single invention in that they are connected in design, operation, and effect, i.e., are not independent inventions. Therefore, in view of Applicants admissions, all claimed peptides are rendered obvious over the teachings of May et al.

Claims 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothe et al. (January 14, 1999; WO 99/01541), in view of Applicants admissions in the election response filed December 1, 2003. The teachings of Rothe et al. are set forth above. Applicants state that that the peptides encompassed by the claims clearly represent a single invention in that they are connected in design, operation, and effect, i.e., are not

Art Unit: 1653

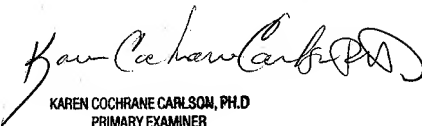
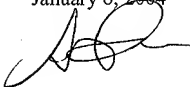
independent inventions. Therefore, in view of Applicants admissions, all claimed peptides are rendered obvious over the teachings of Rothe et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai whose telephone number is (703) 305-4443. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

January 6, 2004



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER